**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

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| **In re Namenda Direct Purchaser Antitrust Litigation** | Civil Action No. 1:15-cv-07488 (CM)(JF) |

**MEMORANDUM OF LAW IN SUPPORT OF NON-PARTY TEVA USA'S MOTION TO DISQUALIFY DIRECT PURCHASER PLAINTIFFS' PROPOSED EXPERT DEBORAH JASKOT**

**(REDACTED)**

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## INTRODUCTION

The plaintiffs in this case allege that a brand-name drug company and several generic drug companies, including Teva Pharmaceuticals USA, Inc. ("Teva USA"), engaged in an anticompetitive scheme to restrict public access to a generic Alzheimer's medication (Namenda IR) by the terms of their patent litigation settlement agreements in which they allegedly agreed to delay market entry until three months before the brand-name drug's exclusivity elapsed. While these plaintiffs (direct purchasers of Namenda IR) named only the brand drug company as defendants, the plaintiffs in the related matter (indirect purchasers of Namenda IR) make the same allegations and named Teva USA (and other generic companies) as a defendant.

This motion arises from the plaintiffs' plan to retain Deborah Jaskot as an expert on regulatory generic drug issues. Ms. Jaskot is a 23-year veteran of Teva USA who served as the highest-level executive in Teva USA's Regulatory Affairs department at the time all of the relevant events in this case took place. In that role, Ms. Jaskot was privy to confidential information central to the issues in dispute in this case, including Teva USA's FDA approval strategies, litigation strategies, and generic drug approval and launch forecasts and plans, among other issues. While Ms. Jaskot has given assurances that she would not intentionally disclose this confidential information in her capacity as an expert in this case, the notion that she could "compartmentalize" the information she obtained during her 23-year history at Teva USA and testify solely based on non-Teva information that the plaintiffs provide to her is "impossible to expect": "An expert cannot build a Chinese wall in his own mind, despite his best efforts to do so." *Auto-Kaps, LLC v. Clorox Co.*, No. 15 CIV. 1737 (BMC), 2016 WL 1122037, at *4 (E.D.N.Y. Mar. 22, 2016). Nor can Ms. Jaskot and the plaintiffs unilaterally agree to limit the defendants' expert discovery and cross-examination, both of which are likely to expose Teva USA's confidential information.

Teva USA raised its concerns about the plaintiffs' plan to retain Ms. Jaskot, engaging in an extensive meet-and-confer process with the plaintiffs. In an attempt to accommodate the interests of all parties, Teva USA proposed a stipulation that would have put appropriate boundaries around the scope of any consultation or testimony Ms. Jaskot could provide, protecting Teva USA's confidential information while permitting Ms. Jaskot to provide her expertise on laws, regulations, and regulatory processes. The plaintiffs, however, rejected Teva USA's proposal, necessitating this motion.

Because the inherent and unavoidable potential for a breach of Teva USA's confidence is clear, "[t]he Court must therefore protect the integrity of the judicial process by ensuring that [Ms. Jaskot] does not use, even unwittingly, confidential information that [she] learned" as a Teva USA employee against Teva USA here. *Auto-Kaps*, 2016 WL 1122037, at *5. Teva USA respectfully requests that the Court disqualify Ms. Jaskot from serving as an expert in this case.

## BACKGROUND

### A. Factual and Procedural Background

Forest Laboratories, LLC began selling Namenda IR—immediate release tablets used to treat symptoms of Alzheimer's disease—in 2004 after receiving FDA approval. Mem. Decision and Order Denying Defendants' Motion to Dismiss 4, ECF No. 106 ("MTD Order"). Generic drug companies, including Teva USA, then sought FDA approval for generic versions of Namenda IR by filing abbreviated new drug applications ("ANDAs") under the abbreviated drug approval pathway established by the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984). MTD Order 10.[1] Forest responded, as permitted under the Hatch-Waxman Act, by filing patent infringement lawsuits

[1] In the interest of brevity, Teva USA does not repeat the parties' prior recitations of the relevant regulatory structure, which is thoroughly described on pages 5-10 of the Court's MTD Order.

against each of the generic manufacturers based on a patent covering Namenda that was set to expire on April 11, 2015. *Id.* at 10-11; Memorandum Decision and Order re Summary Judgment 11, ECF No. 253 ("MSJ Order").

Eventually those patent infringement actions were settled through agreements that were, "in the truest sense, a compromise." MSJ Order 38. The generic manufacturers received a license from Forest to enter the market on January 11, 2015, if Forest did not obtain the six months of pediatric exclusivity they had sought, and on July 11, 2015, if Forest did obtain pediatric exclusivity.[2] "Both of these dates were *earlier* than would have been the case if [Forest] prevailed in [its] patent infringement action, and later than if [Forest] lost the action or if the action failed to resolve before the expiration of [a] stay" of FDA approval that had been ordered while patent litigation proceeded. *Id.*

In August and September 2015, two virtually identical lawsuits were filed in this District asserting state and federal antitrust violations by Forest and manufacturers of generic Namenda. In the first case, indirect purchasers of Namenda ("Indirect Purchaser Plaintiffs") sued Forest[3] and the manufacturers of generic Namenda (the "Generic Competitors"), including Teva USA, asserting state-law antitrust violations (the "IPP Action"). Compl., *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, No. 15-cv-6549-CM (S.D.N.Y. Aug. 20, 2015), ECF No. 6. In the second case (the instant action), direct purchasers of Namenda ("Direct Purchaser Plaintiffs") sued Forest but not the Generic Competitors, asserting federal antitrust violations

[2] As the Court explained in its MSJ Order, a brand-name drug manufacturer can obtain an extra six months of market exclusivity if it conducts pediatric studies designed to demonstrate whether the drug may produce health benefits when used by children. MSJ Order 6. Forest had not sought pediatric exclusivity at the time it entered into settlement agreements with the generic drug manufacturers, but it applied for and was granted pediatric exclusivity in June 2014. *Id.* at 11.

[3] Along with Forest, the Indirect Purchaser Plaintiffs also sued Forest's parent company, Actavis, PLC, and the companies that hold the patent from which Forest has licensed the rights to market Namenda. These companies are collectively referred to herein as "Forest."

(the "DPP Action"). Compl., *J M Smith Corp. v. Actavis, PLC*, No. 15-cv-7488-CM (S.D.N.Y. Sept. 22, 2015), ECF No. 1. The two cases involve virtually identical allegations—indeed, the operative complaints contain dozens of paragraphs that are identical. *Compare, e.g.*, First Amended Compl. ¶¶ 57-58, 59-60, 88-97, 98-101, 105-109, 111-118, 121-139, 141-145, *Sergeants*, No. 15-cv-6549-CM (S.D.N.Y. Feb. 17, 2016), ECF No. 96 ("IPP FAC"), *with* First Amended Compl. ¶¶ 55-56, 58-59, 80-89, 145-148, 153-156,158-165, 168-186, 188-192, *J M Smith*, No. 15-cv-7488-CM (S.D.N.Y. Oct. 14, 2015), ECF No. 29 ("DPP FAC"). The DPP Action was submitted and accepted as related to the IPP Action on the ground that the DPP complaint "challenges the same or similar conduct, is brought against some of the same defendants, and is being filed in the same jurisdiction." ECF No. 9; *see also* MTD Order 15 (noting that the respective plaintiffs filed complaints "on substantially the same grounds").

In both cases, the plaintiffs alleged that Forest and the Generic Competitors conspired to delay entry of generic Namenda by entering into settlement agreements that the Direct and Indirect Purchaser Plaintiffs allege were unlawful and anticompetitive. MTD Order 2-3. They also alleged that Forest violated federal and state antitrust laws "by attempting to restrict access to Namenda IR" through its launch of Namenda XR, a virtually identical drug to Namenda IR that is administered through a once-daily extended-release capsule rather than a twice-daily, immediate-release tablet. MTD Order 2, 4. Specifically, the plaintiffs alleged that Forest attempted an unlawful and anticompetitive "product-hopping" scheme to force patients and physicians to "switch" from Namenda IR (which would lose patent protection in 2015 and be subject to generic competition) to Namenda XR (which was covered by a patent that does not expire until 2029) before generic Namenda IR entered the marketplace. *Id.* at 11-15; *id.* at 8 (noting that "once patients and physicians have switched to a follow-on product, . . . they will not

switch back to the original product"). They further alleged that Forest used the additional exclusivity it obtained through the settlement agreements with the Generic Competitors "to convert as much of the market as possible to Namenda XR prior to market entry of generic versions of Namenda IR because the generic versions of Namenda IR would not be . . . automatically substitutable [for Namenda XR] at the pharmacy." DPP FAC ¶ 5.

The Parties filed consolidated briefing on the defendants' motions to dismiss in both actions, and the Court issued a single order denying the motions. Addressing only the federal antitrust claims in the DPP Action, the Court first held that the Direct Purchaser Plaintiffs stated a federal antitrust claim against Forest for "product hopping." *Id.* at 18-24. The Court further held that the Direct Purchaser Plaintiffs stated a plausible federal antitrust claim that Forest and the Generic Defendants entered into anticompetitive patent litigation settlement agreements under the Supreme Court's decision in *FTC v. Actavis*, 133 S. Ct. 2223, 2237 (2013), which held that patent litigation settlements may be anticompetitive and unlawful if they involve "large and unjustified" payments by the brand-name drug company to a generic drug company in exchange for the generic's agreement not to make any attempt to enter the market for a specific period of time. MTD Order 25-32. The Court then stayed the IPP Action pending resolution of the federal claims asserted in the DPP Action. MTD Order 33. The Court stated that after the factual record developed in the DPP Action and the federal claims were resolved, it would be better able to "determine whether the Indirect Purchaser Plaintiffs' [complementary state-law] claims have merit." *Id.*

Though fact discovery is still ongoing in the active DPP Action, this Court recently resolved motions for partial summary judgment filed by the Direct Purchaser Plaintiffs and by Forest. As relevant here, the Court denied both motions with respect to the claim alleging

anticompetitive settlements between Forest and the Generic Defendants. The Court held that while the settlement agreements were not *per se* anticompetitive, determining their reasonableness under the "rule of reason" would "depend on several complex factual questions that cannot be decided on summary judgment." MSJ Order 40.

### B. Deborah Jaskot's 23-Year Career at Teva USA Working on Regulatory Issues, Including Generic Namenda FDA Approval and Litigation

On June 1, 2017, counsel for the Direct Purchaser Plaintiffs disclosed Deborah Jaskot as an expert in this litigation. Declaration of Sarah K. Frederick ("Frederick Decl."), Ex. G. Ms. Jaskot is a former Teva USA employee who spent almost her entire professional career working in Teva USA's Regulatory Affairs department. Frederick Decl., Ex. H, at 1 (Jaskot curriculum vitae). After working for three years as a coordinator at Cord Laboratories (a generic drug manufacturer that was later acquired by Sandoz), Ms. Jaskot joined Teva USA (then Lemmon Company) in 1989 as an associate in Regulatory Affairs. Ms. Jaskot gradually rose up the ranks at Teva USA, eventually being named Vice President of U.S. Generic Regulatory Affairs—a position she held from 2004 until 2012. *Id.*

In her capacity as Vice President of U.S. Generic Regulatory Affairs (the highest-level company executive in that department), Ms. Jaskot was ultimately responsible for Teva USA's generic drug FDA submissions and related strategic decision-making for Teva's U.S. generic drug products; indeed, she was "the primary liaison between Teva and FDA." *See* Frederick Decl., Ex. H, at 2; *see, e.g.*, Letter from Keith Webber, Ph.D., Deputy Director, Office of Pharmaceutical Science, Center for Drug Evaluation and Research to Deborah Jaskot (May 17, 2012), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/091216Orig1s000ltr.pdf (letter regarding ANDA approval for generic Plavix); Letter from Keith Webber, Ph.D., Deputy Director, Office of Pharmaceutical Science, Center for Drug Evaluation and Research to

Deborah Jaskot, (Jan. 25, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/077983s000ltr.pdf (letter to Ms. Jaskot regarding ANDA approval for generic Gemzar).[4] As a result, she is deeply familiar with Teva USA's "regulatory strategies" for generic drug approvals and launch, Frederick Decl., Ex. H, at 2, and with Teva USA's related patent litigation strategy and patent litigation settlement strategy.[5] Indeed, indicative of her intimate knowledge of Teva USA's generic drug business, regulatory strategy, and patent litigation matters, Ms. Jaskot testified as a fact witness in "85-90 depositions during [her] career at Teva," including patent and antitrust cases. *See id.*

Nor is the problem limited to general polices or practices. Ms. Jaskot was privy to Teva USA's confidential and privileged information regarding the specific generic drug at issue here—Namenda IR, also known by its generic name, memantine IR. Ms. Jaskot's tenure as Vice President of U.S. Generic Regulatory Affairs (2004-2012) overlaps with all of the relevant events here—the 2007 ANDA filings of generic Namenda, including Teva USA's (DPP FAC ¶ 102); Forest's 2008 patent litigation against Teva USA regarding its generic Namenda (DPP FAC ¶ 104); the settlement agreements reached with the Generic Competitors, including Teva

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[4] Ms. Jaskot also submitted numerous citizen petitions or comments to FDA on Teva USA's behalf during her tenure at the company, as is evident simply from searching "Deborah A. Jaskot" on the regulations.gov website: https://www.regulations.gov/searchResults?rpp=50&so=DESC&sb=postedDate&po=0&s=%22Deborah%2BA.%2BJaskot%22&a=FDA. *See also, e.g.*, Letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research to Deborah A. Jaskot (Feb. 6, 2001), https://www.fda.gov/ohrms/dockets/dailys/01/Mar01/030501/pav0001.pdf (letter regarding citizen petition submitted by Ms. Jaskot with respect to ANDA submitted by Mylan Pharmaceuticals, a Teva USA competitor).

[5] *See, e.g.*, Fed. Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at ix n.13 (July 2002), *available at* https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf (describing citizen petition submitted by Ms. Jaskot regarding eligibility for first-generic-applicant exclusivity following settlement of patent litigation); J. Mark Pohl, Food & Drug Law Institute, *Potential Loss of 180-Day Exclusivity* 12-14 & nn. 12, 13, 16, 17, Update Magazine (January/February 2010), *available at* http://www.licensinglaw.net/files/Potential_Loss_180_Day_Exclusivity.pdf (discussing numerous letters submitted to FDA by Ms. Jaskot regarding Teva USA's positions, in response to patent litigation developments, with respect to Paragraph (iv) certification and generic exclusivity); First Amended Complaint ¶ 21, *Hoffman-La Roche Inc. v. Teva Pharm. USA, Inc.*, No. 2:08-cv-04059-SRC-MAS (D.N.J. filed Sept. 24, 2008) (describing Paragraph (iv) certification received by brand-name drug company Hoffman-La Roche from Ms. Jaskot, which triggered Hoffman-La Roche's right to file patent litigation against Teva USA).

USA's in 2009 (DPP FAC ¶ 113); and FDA's tentative and final approvals of Teva USA's generic Namenda in March 2010 and October 2011 (DPP FAC ¶¶ 132, 133). She was privy to privileged information concerning the patent litigation at issue. Frederick Decl., Ex. K (privilege log listing numerous privileged documents of which Ms. Jaskot was a recipient, including correspondence reflecting legal advice regarding Teva USA's generic Namenda ANDA and product).

Ms. Jaskot's employment with Teva USA ended on November 16, 2012. In executing her separation agreement, Ms. Jaskot [redacted] Frederick Decl., Ex. F ¶ 13(a).

### C. Teva USA's Objection to Ms. Jaskot and Efforts to Reach a Mutually-Agreeable Resolution

In light of Ms. Jaskot's long history of working on regulatory issues and patent litigation at Teva USA, including with respect to the specific drug at issue in this case; the confidential and privileged information Ms. Jaskot learned in that role; and the prejudice that would result if Ms. Jaskot were to serve as an expert in the DPP Action, Teva USA objected to the use of Ms. Jaskot as an expert in this case. Frederick Decl., Ex. J (June 8, 2017 email of Sarah K. Frederick). Teva USA and the Direct Purchaser Plaintiffs met and conferred on numerous occasions. Through their respective counsel, they exchanged more than one dozen emails and participated in two telephone conferences, including one telephone conference with Ms. Jaskot. Frederick Decl. ¶¶ 9-16 & Ex. J.

During these exchanges, counsel for the Direct Purchaser Plaintiffs stated that they had not shared with Ms. Jaskot the fact of Teva USA's status as a defendant in the related case

brought by Indirect Purchaser Plaintiffs. Counsel represented that the plaintiffs would not show Ms. Jaskot any of Teva USA's produced documents, and that they would not ask Ms. Jaskot to opine on Teva-specific issues; rather, they planned to cabin her testimony to general regulatory issues and issues relevant to the other Generic Competitors based on documents relating to those Generic Competitors. Frederick Decl. ¶ 11 & Ex. J. Counsel for Teva USA stated that Teva's concerns are not that Ms. Jaskot would be shown confidential documents (to which she already had access during her tenure at Teva USA and on which her name in several instances appears); rather, Teva USA's concerns are, among other things, that Ms. Jaskot might use (even inadvertently) confidential information she obtained while at Teva USA, and that Ms. Jaskot's testimony about the conduct and beliefs of generic manufacturers would implicitly or explicitly be attributed to Teva USA, through either direct or cross-examination. *Id.* ¶¶ 10, 13 & Ex. J.

In an effort to come to a resolution that would obviate the need for this motion, Teva USA proposed a written agreement among Teva USA, the Direct Purchaser Plaintiffs, Ms. Jaskot, and Forest that might balance Teva USA's interest in protecting its confidential and privileged information and the Direct Purchaser Plaintiffs' interest in obtaining the expert services of Ms. Jaskot. Frederick Decl. ¶ 15 & Ex. N. The Direct Purchase Plaintiffs would not agree to Teva USA's proposed stipulation and did not propose any alternative language. *Id.* ¶ 16 & Ex. J. Consequently, Teva USA files this motion and respectfully requests that the Court disqualify Ms. Jaskot from serving as an expert in this case.

## LEGAL STANDARD

This Court has the "inherent power" to disqualify an expert witness who "formerly had a relationship with an adverse party." *Grioli v. Delta Int'l Machinery Corp.*, 395 F. Supp. 2d 11, 13 (E.D.N.Y. 2005). The Court considers three factors in deciding whether to disqualify an expert witness based on such a conflict of interest: (a) whether there was a "reasonable

expectation of a confidential relationship between the movant and the expert," (b) whether "the movant in fact disclosed confidential information to the expert," and (c) whether the public's interest in judicial integrity and fairness balanced against a party's right to the assistance of experts and an expert's right to pursue her professional calling weighs against disqualification. *Auto-Kaps*, 2016 WL 1122037, at *2. If the movant meets its burden of establishing the first two elements, the party seeking to retain the expert must present evidence establishing that the public interest weighs against disqualification. *Id.* at *4. A disqualification motion may be made by an interested non-party who may be prejudiced in pending litigation by the proposed expert's testimony. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Teva Pharm. USA, Inc.*, Nos. 14-874-SLR/SRF, 15-250-SLR/SRF, 2015 WL 5163035, at *3 (D. Del. Sept. 3, 2015) (granting disqualification motion filed by interested non-party).

## ARGUMENT

### I. Teva USA Had an Objectively Reasonable Expectation of a Confidential Relationship with Ms. Jaskot, Teva USA's 23-Year Veteran Former Regulatory Affairs Executive

The "objectively reasonable belief" requirement is "not a high hurdle to clear." *AstraZeneca Pharm., LP v. Teva Pharm. USA, Inc.*, No. CIV. A. 05-5333 (JAP), 2007 WL 4292384, at *2 (D.N.J. Dec. 4, 2007). Where, as here, the proposed expert is a former employee, expert, or consultant who was subject to an express, written confidentiality agreement, this factor is easily established. *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, No. 95 CIV. 8833 (RPP), 2000 WL 42202, at *1 (S.D.N.Y. Jan. 19, 2000) (former consultant's agreement with movant contained a confidentiality provision); *AstraZeneca Pharm.*, 2007 WL 4292384, at *2 (former outside consultant was "subject to express, written confidentiality agreements"). Indeed, "the confidential relationship would seem to be stronger between an employer and a long-time employee than between an employer and a sometime expert." *Dyna-Drill Techs. Inc.*

*v. Conforma Clad Inc.*, No. CIV.A. H-03-05599, 2005 WL 5979403, at *1 (S.D. Tex. May 16, 2005); *e.g.*, *Pellerin v. Honeywell Int'l Inc.*, No. 11CV1278-BEN (CAB), 2012 WL 112539, at *1 (S.D. Cal. Jan. 12, 2012) (factor satisfied where former employee, "in relation to his employment[,] entered into confidentiality agreements with the defendants that bind him to keep confidential information he obtained during his employment").

Ms. Jaskot was subject to precisely such an agreement. While employed at Teva USA, she signed an "Employee Confidential Information Agreement" that [redacted] Frederick Decl. Ex. E.[6] Furthermore, in executing her separation agreement, Ms. Jaskot [redacted] Frederick Decl. Ex. F, ¶ 13(a). Thus, Teva USA plainly had an objectively reasonable expectation in a confidential relationship with Ms. Jaskot.

## II. Teva USA in Fact Disclosed Relevant Confidential Information to Ms. Jaskot.

The second requirement is met if the proposed expert received confidential information "relevant to the current litigation" during the course of its relationship with the party seeking disqualification. *Auto-Kaps*, 2016 WL 1122037, at *2; *accord Dyna-Drill*, 2005 WL 5979403, at *2. This requirement is easily satisfied here. This litigation involves questions about whether

[6] This Agreement refers to Ms. Jaskot's employer as "Lemmon," which merged with several other companies to create the company that is today known as Teva Pharmaceuticals USA, Inc. http://www.tevapharm.com/about/history/.

the settlement agreements entered into by the Generic Competitors, including Teva USA, were reasonable in light of the Generic Defendants' views about anticipated regulatory approval dates, launch dates, and sales; in light of their understanding of first-filer exclusivity and pediatric exclusivity; and in light of the strength of the Generic Competitors' ANDAs, among other issues. As is clear from the third-party discovery served on Teva USA, relevant matters include Teva USA's complete regulatory files for generic Namenda (including its ANDA); Teva USA's projections and plans regarding regulatory approval, launch, and sales; Teva USA's understanding regarding the interpretation of regulatory exclusivities; and Teva USA's efforts to develop and obtain approval for generic Namenda, among other things. Frederick Decl. Ex. A (Direct Purchaser Plaintiffs' document subpoena); Frederick Decl., Ex. B (Forest's document subpoena); Frederick Decl. Ex. C (Direct Purchaser Plaintiffs' deposition subpoena); Frederick Decl. Ex. D (Forest's deposition subpoena).

These are the very issues Ms. Jaskot worked on while employed at Teva USA. Ms. Jaskot's curriculum vitae alone makes clear that as the highest-level executive in Regulatory Affairs, she was ultimately responsible for regulatory approval and related strategic decision-making for all of Teva's U.S. generic drugs, and that she was heavily involved in Teva USA's generic patent litigation. Frederick Decl., Ex. H, at 2 (listing, as significant achievements, that Ms. Jaskot "achieve[d] hundreds of ANDA approvals," was the "primary liaison between Teva and FDA," and gave "approximately 85 depositions in both patent and product liability cases"). Given Ms. Jaskot's position, it is "not difficult to infer that [she] was given or exposed to confidential information" relating to Teva USA's regulatory practices, strategies, and understanding. *Auto-Kaps*, 2016 WL 1122037, at *4. Moreover, there is ample evidence, even in the public domain, that she was in fact the recipient of confidential information regarding

these issues, including Ms. Jaskot's ANDA-related correspondence with FDA and Ms. Jaskot's correspondence with brand-name competitors. *See supra* pp. 6-7 & nn. 4-5 (citing numerous FDA communications, patent litigation documents, and other materials demonstrating Ms. Jaskot's involvement in generic drug approval and associated patent litigation).

Indeed, Ms. Jaskot was privy to Teva USA's confidential information regarding the specific generic drug at issue here—Namenda, also known by its generic name, memantine IR. Ms. Jaskot's tenure as Vice President of U.S. Generic Regulatory Affairs (2004-2012) overlaps with all of the relevant events here—the 2007 ANDA filings of generic Namenda (DPP FAC ¶ 102); Forest's 2008 patent litigation against Teva USA regarding its generic Namenda (DPP FAC ¶ 104); the settlement agreements reached with the Generic Competitors, including Teva USA's in 2009 (DPP FAC ¶ 113); and FDA's tentative and final approvals of Teva USA's generic Namenda in March 2010 and October 2011 (DPP FAC ¶¶ 132, 133). As the highest-level executive in U.S. Generic Regulatory Affairs, Ms. Jaskot had access to confidential information regarding these events and, indeed, regularly received privileged or confidential information regarding generic Namenda during this time period. *See* Declaration of H. Bruce Gordon ¶¶ 3-4 (stating that a search of Ms. Jaskot's emails revealed more than 1,000 confidential or privileged documents mentioning generic Namenda or its generic reference name, memantine); *see, e.g.*, Frederick Decl., Ex. L (email received by Ms. Jaskot discussing FDA submissions for memantine); Frederick Decl., Ex. K (privilege log showing Ms. Jaskot as the recipient of numerous privileged communications regarding Teva USA's generic Namenda ANDA and product).[7]

[7] While a high-level regulatory executive's exposure to confidential and privileged regulatory and litigation strategy communications and documents is fairly self-evident, Teva USA is prepared to provide examples of such privileged materials for *in camera* review should the Court find it helpful.

Given the nature of the Direct Purchaser Plaintiffs' federal antitrust claims (and the parallel claims in the related IPP action, in which Teva USA is named as a defendant), Ms. Jaskot's responsibility over Regulatory Affairs at Teva USA, and Ms. Jaskot's access to and involvement in Teva USA's development of and regulatory submissions regarding the specific drug at issue in this case, it cannot seriously be questioned that the second requirement for disqualification is met. *See, e.g.*, *AstraZeneca*, 2007 WL 4292384, at *3 (confidential-information requirement satisfied where former consultant "was exposed to highly sensitive marketing, business, and clinical information that clearly was not intended for publication"); *Auto-Kaps*, 2016 WL 1122037, at *3-*4 (email communications made clear that former consultant was "given or exposed to confidential information relating to [the movant's] strategy regarding its intellectual property" and product components that were "directly related to the technology at issue"). Indeed, the Direct Purchaser Plaintiffs have never disputed that Ms. Jaskot was privy to confidential information regarding generic Namenda and the issues relevant to this dispute. Frederick Decl. ¶ 11. Instead, they have offered a bevy of reasons—all of which have been roundly rejected by courts—why Ms. Jaskot should nevertheless be allowed to serve as an expert in this action.

First, the Direct Purchaser Plaintiffs have suggested that Teva USA's interests will be adequately protected because they will not show Ms. Jaskot any documents produced by Teva USA and her testimony will be based only on non-Teva documents that they provide to her from this litigation rather than on Teva USA's confidential materials. But this fundamentally misunderstands the conflict that exists in this case. Teva USA is not concerned about preventing Ms. Jaskot from seeing Teva USA's confidential documents—she was privy to these documents in her capacity as Teva USA's Vice President of Regulatory Affairs. Indeed, it is precisely

because Ms. Jaskot was privy to Teva USA's confidential information (including with respect to generic Namenda) that she must be disqualified in this action. As courts have repeatedly observed, the notion that former employees, consultants, and experts of adverse parties can "parse [their] knowledge of [an adverse party's] confidential information to only rely upon what is provided to [them] in litigation" is "unpersuasive": "the human brain does not compartmentalize information in that manner." *Pellerin*, 2012 WL 112539, at *3. Particularly where, as here, the confidential information received "is at the very heart of the litigation," a former employee "cannot build a Chinese wall in his own mind, despite his best efforts to do so." *Auto-Kaps*, 2016 WL 1122037, at *4; *see also Dyna-Drill*, 2005 WL 5979403, at *2 (serving as an expert "without reference to any confidential information" disclosed while the proposed expert was an employee "seems to the Court to be an impossible feat").

The same is true of the plaintiffs' suggestion that Ms. Jaskot could simply testify based on her general experience working on regulatory issues rather than on confidential information she received from Teva USA. Virtually all of Ms. Jaskot's professional career was spent at Teva USA. She joined Teva USA in 1989 as a Regulatory Affairs associate after having worked for just three years as a coordinator at Cord Laboratories. For the next 23 years, Ms. Jaskot rose up the ranks at Teva USA, culminating in her eight-year tenure as Vice President of U.S. Generic Regulatory Affairs. Since separating from Teva USA in 2012, Ms. Jaskot has not worked for any other pharmaceutical company or in any other regulatory position; instead, she opened a consulting company to provide consulting services based on her prior experience (which she largely obtained at Teva USA). In short, "the only expertise [Ms. Jaskot] could have gained that would be relevant to [her] testimony in this lawsuit was gained while [she] was an employee" of Teva USA. *Dyna-Drill*, 2005 WL 5979403, at *2. And here, that expertise is inseparable from

her work on the issues in this case, which she ultimately oversaw, and which all occurred during her tenure at Teva USA.

The Direct Purchaser Plaintiffs have also contended that Teva USA has not pointed to any way in which Ms. Jaskot's confidentiality obligations have been or will be breached by her involvement in this action. But counsel has explained Teva USA's concerns, and plaintiffs misunderstand the relevant inquiry: "On a motion to disqualify, . . . the inquiry is not into what confidential information the expert has disclosed, but what was disclosed to him." *Auto-Kaps*, 2016 WL 1122037, at *3. The rules governing disqualification of an interested party's former employee, consultant, or expert "are designed to protect against *the potential breach* of such confidences, even without any predicate showing of actual breach. . . . The threat or potential threat that confidences may be disclosed is enough." *Marvin Lumber & Cedar Co. v. Norton Co.*, 113 F.R.D. 588, 591 (D. Minn. 1986) (emphasis added). Indeed, the risk of even *inadvertent* exposure—which *inherently* exists when an expert is testifying against a former employer from which she received confidential information—is sufficient to justify disqualification. *Pellerin*, 2012 WL 112539, at *3; *see also Auto-Kaps*, 2016 WL 1122037, at *4 (where former consultant had been included on confidential communications about the product at issue in litigation, there was "a substantial risk that Foster may inadvertently disclose confidential information he acquired during his consulting work for [the moving party] while serving as [an] expert").

But here, we have more than the risk of inadvertent disclosure; we have an expert who will be subject to a discovery deposition and cross-examination at trial. When Ms. Jaskot is cross-examined about her opinions, she will naturally be asked about where she obtained the expertise that informed her opinion, and she could quite easily be asked by Forest on cross-

examination whether her opinion is consistent with the opinion she espoused while leading Teva USA's Regulatory Affairs department. Faced with these types of questions, she would either have to answer, exposing Teva USA's confidential and privileged information, or refuse to answer, perhaps citing her confidentiality obligations to Teva USA. Either response could lead a member of the jury to draw an inference regarding Teva USA's beliefs and practices, or would improperly focus attention on *Teva's* practices, rather than a neutral and objective expert's opinion.

Finally, the Direct Purchaser Plaintiffs may contend that Ms. Jaskot's former confidential relationship with Teva USA and the confidential information she obtained at Teva USA are simply irrelevant because Teva USA is not a defendant in the DPP Action. Any such argument is meritless. Courts have entertained (and granted) disqualification motions filed by non-parties with an interest in the litigation where the parties to the litigation do not adequately represent the non-party's interest in maintaining the confidentiality of its protected information and where disclosure of confidential information, even if inadvertent, could adversely impact the non-party in related litigation. *See, e.g.*, *Merck Sharp & Dohme Corp.*, 2015 WL 5163035, at *2 (granting non-party's motion to disqualify). Furthermore, in this case, Teva USA is a non-party in name only. The Direct Purchaser Plaintiffs allege that the named defendants engaged in an unlawful and anticompetitive scheme with Teva USA and other Generic Competitors; they and the defendants in this action have sought documents related to Teva USA's conduct, practices, policies, beliefs, and strategies (and Teva has produced more than 3,800 pages of documents of such documents), as well as Rule 30(b)(6) deposition testimony covering well over a dozen topics. Frederick Decl. ¶ 5 & Exs. A-D. And, of course, the related IPP action cannot be ignored. The allegations in this case are virtually identical (often word-for-word) to those

included in the IPP Complaint pending in this District in which Teva USA *has* been named as a defendant, and which has been stayed expressly *so that the factual record can be established in this case*. There is every reason to believe that any public testimony by Ms. Jaskot given in the DPP action would be available to the plaintiffs in the IPP action as well, which magnifies the concern here. For all these reasons, Teva USA's interest in this action is clear—and its interest in protecting its confidential information and avoiding the prejudice that would result from Ms. Jaskot's use or disclosure, even if inadvertent, is just as strong as if Teva USA were a named defendant.

## III. The Public Interest Weighs in Favor of Disqualification.

Because Teva USA has established the first two disqualification requirements, the Direct Purchaser Plaintiffs must provide evidence of "countervailing concerns" that weigh against disqualification. *Auto-Kaps*, 2016 WL 1122037, at *4-*5. These public interest concerns include the right of parties to have access to expert witnesses who possess specialized knowledge, the right of experts to pursue their professional calling, and the public interest in fairness and judicial integrity. *Id.* The Direct Purchaser Plaintiffs cannot meet their burden here because disqualifying Ms. Jaskot would neither deprive the Direct Purchaser Plaintiffs of a qualified expert, nor deprive Ms. Jaskot of her livelihood.

First, granting Teva USA's motion would not deprive the Direct Purchaser Plaintiffs of a qualified expert. Ms. Jaskot's expertise (in generic pharmaceutical regulatory matters) is not in a field in which there is a dearth of experts with relevant experience. *See Bristol-Myers Squibb*, 2000 WL 42202, at *5 (granting motion for disqualification where the plaintiff "ha[d] not shown that there are not other experts in the treatment of ovarian cancer available to testify as independent experts"); *Auto-Kaps*, 2016 WL 1122037, at *4 ("Plaintiff has offered no representation that Foster's expertise is rare, or that there are few experts on the topic of

dispensing systems.").[8] The U.S. pharmaceutical market is a $333 billion a year industry, with $70 billion in generic sales last year alone,[9] and as Teva well knows through its own patent and antitrust litigation experience, regulatory experts are readily available. Counsel for the plaintiffs and Ms. Jaskot expressly stated when meeting and conferring regarding this motion that Ms. Jaskot's opinion "would be the same had she worked at any other generic manufacturer instead of Teva." Frederick Decl., Ex. J (June 26, 2017 email from Dan Chiorean); Frederick Decl. ¶ 14. Indeed, given that such regulatory expertise is so readily available, it is likely that Ms. Jaskot's "expertise in this field is of particular value to [the plaintiffs] mainly *because of* [her] former relationship with [Teva USA], but that is the reason to disqualify [her]." *Pellerin*, 2012 WL 112539, at *3 (emphasis added). The Direct Purchaser Plaintiffs should certainly have access to expert witnesses who possess specialized knowledge; but they should not be permitted to retain an expert witness whose specialized knowledge is the result of her former employment at a company whose conduct is directly at issue in this litigation. In fact, they have already disclosed another expert with a regulatory background for this litigation, and the same counsel have retained regulatory experts in other antitrust litigation without the need for Ms. Jaskot. Frederick Decl., Ex. G (disclosing Janet K. DeLeon as an expert in this case); Frederick Decl., Ex. I (Ms. DeLeon's curriculum vitae).

Second, Ms. Jaskot will not be "deprived of [her] pursuit of [her] professional calling" by being disqualified from serving as a witness in this case. *Bristol-Myers Squibb*, 2000 WL 42202, at *5. Ms. Jaskot has operated her own consulting company for more than the past four years,

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[8] The Direct Purchaser Plaintiffs also will not be unduly burdened by having to retain an expert. The readily apparent conflict of interest in this case could hardly come as a surprise to the Direct Purchaser Plaintiffs given that Ms. Jaskot's curriculum vitae makes clear that her expertise is almost entirely by virtue of her experience at Teva USA.

[9] *See* International Trade Administration, U.S. Dep't of Commerce, *2016 Top Marks Report Pharmaceuticals* 3-4, *available at* http://trade.gov/topmarkets/pdf/Pharmaceuticals_Executive_Summary.pdf.

during which time she has acted as an expert witness. Frederick Decl., Ex. H. Not once in this time period has Teva USA sought to preclude Ms. Jaskot from pursuing her consulting business or to disqualify her from serving as an expert. Teva USA has no interest in preventing Ms. Jaskot from being an expert in any case, but it has a well-recognized right to prevent Ms. Jaskot from testifying effectively against Teva USA in this case, which involves issues and products about which Ms. Jaskot was privy to confidential information while leading Teva USA's Regulatory Affairs department, where she was exposed to attorney-client privileged information, and, indeed, in which she could be a fact witness given her role in the ANDA at issue.

Third, principles of fairness and judicial integrity weigh heavily in favor of disqualification here. For a party like Teva USA whose conduct is at issue in the litigation, "[t]he disqualification of an expert is not to provide a remedy or punishment for a confidential disclosure, but to prevent the 'risk of prejudice from possible disclosure' and the 'fundamental unfairness' that would arise as a result." *Auto-Kaps*, 2016 WL 1122037, at *3. And the risk of prejudice and unfairness is particularly acute in this case. Even if it were hypothetically possible to ensure that Ms. Jaskot did not actually disclose confidential information, it would be simply impossible for the jury to hear testimony from Teva USA's former Regulatory Affairs executive about how generic pharmaceutical companies generally might view a particular issue (such as generics' interpretation of pediatric exclusivity, or whether and when earlier market entry would be possible) and not impute that testimony to how Teva USA *actually viewed* these issues when pursuing FDA approval of generic Namenda and entering into a settlement agreement with Forest over related patent litigation. Given Ms. Jaskot's long history at Teva USA at the highest levels of the company, the jury will see Ms. Jaskot's testimony as, effectively, Teva USA testifying against itself at trial. Allowing Ms. Jaskot to testify here would undermine the role of

an expert witness, as opposed to a fact witness, and thus the fairness and judicial integrity of this proceeding as a whole.

## CONCLUSION

For the foregoing reasons, Teva USA requests that the Court issue an order disqualifying Ms. Jaskot as an expert for Direct Purchaser Plaintiffs and precluding the Direct Purchaser Plaintiffs' consultation with Ms. Jaskot.

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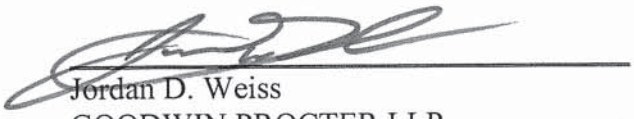
Respectfully submitted,



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